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Indian Standard

SPECIFICATION FOR HOT AIR STERILIZERS

(First Revision)

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(First Revision)

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Indian Standard

SPECIFICATION FOR HOT AIR STERILIZERS

(First Revision)

0. FOREWORD

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 21 November 1978, after the draft finalized by the Hospital Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 Formulation of standards on hospital equipment has been taken up on the recommendations of the Advisory Committee for the Development of Surgical Instruments, Equipment and Appliances of the then Ministry of Industry and Supply, Government of India.

0.3 This Indian standard was first published in 1965 and now it has been revised keeping in view the latest developments in the manufacture of electrically heated hot air sterilizers (sterilizing ovens). In this revision, performance test for thermostats used has been included and the insulation resistance test has been modified.

0.4 This standard covers the performance, general and safety requirements for electrically heated hot air sterilizers, also called sterilizing ovens, with a view to ensuring reliable operation, personal safety against electric shock, excessive temperature and fire. Dimensions of component parts have not been specified. It is recognized that some parts of sterilizers may have to be replaced during use. For this reason, it is essential that the manufacturers should so design their sterilizers that the spare parts of any particular size are interchangeable within one's manufacture.

0.5 Adequate provisions have been made throughout the standard for the safety and satisfactory design of the apparatus, bearing in mind the fact that a good deal of latitude is to be allowed to the individual manufacturer of sterilizers to introduce innovations and refinements.

0.6 General and safety requirements for household and similar electrical appliances (*fourth revision*) (IS : 302-1973) to which references have been made in this standard with regard to general and safety requirements as well as methods of test is a necessary adjunct to this standard. Should, however, any deviations exist between the requirements of IS : 302-1973* and those of this standard, provisions of the latter shall apply.

0.7 In the preparation of this standard assistance has been derived from BS 3421 : 1961 'Specification for performance of electrically heated sterilizing ovens' issued by the British Standards Institution.

0.8 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960†. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard lays down requirements for electrically heated hot air sterilizers (sterilizing ovens) designed to work at voltages not exceeding 250 V ac single phase 50 Hz with a maximum load of 5 kW, intended for hospital and laboratory use. Continuous sterilizers are not covered in this standard.

2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions shall apply.

2.1 Oven — A closed heating chamber in which heat from a source is transferred to the load, predominantly by convection.

2.2 Hot Air Sterilizer (Sterilizing Ovens) — An oven designed principally to destroy bacteria, viruses and fungus by application of dry heat at temperature ranging between 140° and 200°C.

2.3 Working Space — The space within the oven which is above the lowest shelf, if provided, and not less than 5 cm from any heating surface or 3 cm from any non-heating surface of a roof, wall, partition or cover.

2.4 Oven Temperature — The mean of the maximum and minimum temperatures of the air recorded at the centre of the working space over one complete cycle of the thermostat.

2.5 Temperature Variation — The difference in temperature of the air at the centre of the working space and at any other point of the working space at any instant.

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*General and safety requirements for household and similar electrical appliances (*fourth revision*).

†Rules for rounding off numerical values (*revised*).

2.6 Temperature Differential — The cyclic change of temperature at any point in the working space, regulated by the operation of the thermostat.

2.7 Temperature Drift — The change in oven temperature which may take place in continuous operation over a long period.

2.8 Temperature Overshoot — The extent to which the maximum temperature attained by air at the centre of the working space during the initial heating up, exceeds the oven temperature obtained when steady operating condition of the thermostat is reached.

3. RATING

3.1 Voltage Rating — The provisions of **3.1** of IS : 302-1973* shall apply.

3.2 Rated Input — Rated wattage of the sterilizers shall be 1 500 W onwards.

4. MATERIALS

4.1 The provisions of **5.1** of IS : 302-1973* shall apply.

5. CONSTRUCTION

5.1 The relevant provisions of **7** of IS : 302-1973* and those given in **5.2** to **5.6** shall apply.

5.2 Cabinet

5.2.1 The inner surface of the cabinet and its fittings shall be smooth and impervious, and any paint, rendering or coating used on the interior shall be capable of withstanding the maximum temperature for which the oven is designed.

5.2.2 Ventilation of the cabinet shall be by means of one or more ports at the bottom and the top of the cabinet. In large cabinets circulating fans may be provided to assist convection and ventilation so that temperature variation is kept within limits. The ports at the top of the cabinet shall be adjustable to regulate ventilation.

5.2.3 Shelves, if provided, shall be made of stout wire mesh, expanded metal or perforated sheet metal, and shall be adequately protected against corrosion from heat and humidity (*see also* **37** of IS : 302-1973*). The design of lugs, brackets or runners for shelves shall be such that heavily laden shelves do not tilt during withdrawal.

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*General and safety requirements for household and similar electrical appliances (*fourth revision*).

5.3 Heating Elements — The heating elements shall be so designed and located that overheating in their vicinity is minimized. The heating element or that part of it which is fixed on the inside bottom of the oven shall be covered by suitable baffles or perforated covers so that fresh air entering through the bottom ports is preheated and uniformly distributed in the working space and undue heating of materials at the bottom of the working space is avoided. If coil, embedded or strip type elements are used, these shall be easily accessible for replacement.

5.4 Wiring and Components — The wiring and components used in an oven shall be constructed or fixed in such a manner that they shall be able to withstand continuously the temperatures to which they are likely to be exposed when the oven working space is maintained at its designed maximum temperature.

5.5 Thermostats

5.5.1 The thermostat contacts and the contacts of any auxiliary device such as relay or contractor shall be readily accessible for inspection, cleaning or replacement by the removal of a simple cover retained by one or more screws.

5.5.2 The thermostat contacts shall be of silver, platinum or other suitable material that will not be easily fouled or welded by arcing.

5.5.3 If a mercury switch is used in a thermostat or in an auxiliary device it shall be securely mounted and protected so that it cannot be damaged easily in normal handling or transport of the oven.

5.5.4 If the thermostat contacts are slow acting, a condenser of sufficient capacity shall be connected across them to prevent excessive arcing and to minimize radio interference.

5.5.5 If the stem, bulb, or other sensing part of the thermostat is fixed in or protrudes into the working space, it shall be adequately protected from accidental damage during loading or unloading the oven.

5.5.6 If the thermostat adjusting screw, knob or other adjusting device is exposed to unintentional or accidental disturbance of setting, a scale shall be provided to check the setting.

5.5.7 The external provision for adjustment of temperature shall be such that any desired temperature within the range of the oven can be attained within 1°C.

5.6 Thermometer — A temperature measuring device which shall be mercury thermometer or dial type thermometer, capable of reading temperatures with an accuracy of at least 1°C shall be provided on the oven. Alternately, arrangement shall be provided for fixing such a thermometer on the cabinet so that its sensing element is at least 5 cm below the top of the inner chamber.

6. GENERAL AND SAFETY REQUIREMENTS

6.1 Protection Against Electric Shock — The provisions of 8 of IS : 302-1973* shall apply.

6.2 Temperature Limit — The temperature of handles, grips and other like parts shall not exceed the values given in **10.1** read with Table 3 of IS : 302-1973*.

6.3 Electrical Insulation — The provisions of **11** and **44** of IS : 302-1973* shall apply.

6.4 Stability — The provisions of **14** of IS : 302-1973* shall apply.

6.5 Mechanical Strength — The provisions of **15** of IS : 302-1973* shall apply.

6.6 Supply Connections — The provisions of **20** of IS : 302-1973* shall apply.

6.7 Terminals — The provisions of **21** of IS : 302-1973* shall apply.

6.8 Earthing — The provisions of **22** of IS : 302-1973* shall apply.

6.9 Screws and Connections — The provisions of **23** of IS : 302-1973* shall apply.

6.10 Resistance to Rusting — The provisions of **37** of IS : 302-1973* shall apply.

7. PERFORMANCE REQUIREMENTS

7.1 Heating-Up Time — The heating-up time for the hot air sterilizers for a temperature rise of not less than 100°C shall not exceed 30 minutes when the sterilizer is not loaded.

7.2 Thermal Performance — The oven shall satisfactorily pass the test specified in **9.2.3**.

8. MARKING AND INSTRUCTIONS FOR USE

8.1 Each oven shall be marked indelibly and clearly in accordance with **25** of IS : 302-1973*, on its outer surface or on a name plate firmly attached to it.

8.1.1 The marking shall also show the minimum ambient temperature at which the appliance is suitable for operation.

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*General and safety requirements for household and similar electrical appliances (*fourth revision*).

8.1.2 The ovens may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

8.2 Marking of Earth Terminal — The symbol ⏚ shall be marked prominently on or adjacent to the earth terminal, if provided.

8.3 Instruction for Use — Each oven shall be provided with the necessary instructions including precautions to be taken for its proper use. If the thermostat has adjustments for altering its range or sensitivity, the instructions for carrying out such adjustments shall also be included. The instruction leaflet shall include a recommended list of spare parts.

9. TESTS

9.1 General Conditions for Tests

9.1.1 *Test Voltage* — The tests shall be carried out either at the rated voltage or at the maximum voltage of the range unless otherwise specified in the relevant clauses. The test voltage shall not vary by more than ±10 percent during the test.

9.1.2 *Ambient Temperature* — The ambient temperature during the performance tests shall be 27° ± 2°C.

9.1.3 *Test Temperature* — The temperature variation test and temperature differential test shall be carried out at the maximum temperature setting of the sterilizer ±5°C. The temperature drift test, the temperature overshoot test, and the reproducibility of temperature test shall be done at the midpoint of the temperature range of the oven.

9.1.4 *Measurement of Temperatures* — The measurements of temperatures for the purpose of the temperature variation and temperature differential tests shall commence two hours after the oven has been switched on or one hour after the final adjustment of the thermostat, whichever is later.

9.1.4.1 The oven temperature, temperature drift and temperature overshoot shall be measured with a long stem mercury-in-glass thermometer, with the unshielded bulb as near as possible to the centre of the working space. The thermometer shall have a bulb capacity not greater than 0·5 ml, a maximum error not over 0·5°C and the error over any interval of 10°C shall not vary by more than 0·5°C. Separate thermometers conforming with the above requirements may be used at different test temperatures if this is found convenient. It shall also be permissible to use a thermocouple, thermistor or other compact sensing element with a suitable temperature indicator or recorder provided its response to temperature changes and its accuracy are not inferior to the thermometer described.

9.1.4.2 The temperature variation and temperature differential shall be measured with thermocouples, thermistors or other compact sensing elements capable of measuring temperature differences of 0·2°C at the test temperature. For the purpose of measurements, one sensing element shall be placed as near as possible to the centre of the working space and the other successively at the following points:

a) Each of the four upper corners of the working space;

b) Each of the four centre, of the four sides of the working space; and

c) Each of the four points vertically above the four lower corners of the working space at a height of 2 cm above the bottom of the working space.

In the case of cylindrical ovens the temperature shall be measured, instead, at 10 points equally distributed on the cylindrical periphery of the working space and two points on the axis of the cylinder one at each end of the working space.

9.1.5 *Arrangement of the Oven* — The oven shall be placed on a table or stand one metre above floor level and located so as to be protected from direct sun rays or draughts, when carrying out the performance tests. It shall have all shelves, if provided, in position, but not loaded; and the top ventilation ports shall be adjusted according to the manufacturer's instructions accompanying each oven.

9.2 Schedule of Tests — The schedule of tests to be carried out on the ovens for proving conformity with the requirements of this standard is given in Table 1 with reference to relevant clauses of IS : 302-1973* and this standard.

9.2.1 *Visual Examination and Inspection* — Each oven shall be examined and inspected for general construction and marking requirements specified in this standard.

9.2.2 *Insulation Resistance Test* — While conducting this test in accordance with **11** and **44** of IS : 302-1973*, the appliance shall not be subjected to humidity.

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*General and safety requirements for household and similar electrical appliances (*fourth revision*).

TABLE 1 SCHEDULE OF TESTS

(*Clause* 9.2)

TEST	METHOD
Routine Test	
Visual examination and inspection	**9.2.1**
Protection against electric shock	**40** of IS : 302-1973*
High voltage	**42.3** of IS : 302-1973*
Insulation resistance	**11** and **44** of IS : 302-1973* and **9.2.2**
Leakage current	**44** of IS : 302-1973*
Earthing connection	**38** of IS : 302-1973*
Type Test	
Mechanical strength	**36** of IS : 302-1973*
Heating-up time	**9.2.3**
Performance test for thermostat	**49** of IS : 302-1973* and **9.2.4**
Temperature variation	**9.2.5**
Temperature differential	**9.2.6**
Temperature drift	**9.2.7**
Test for time of temperature recovery	**9.2.8**
Test for reproducibility of temperature setting	**9.2.9**
Temperature overshoot	**9.2.10**

*General and safety requirements for household and similar electrical appliances (*fourth revision*).

9.2.3 *Heating-up Time* — The oven shall be at ambient temperature. The thermostat shall be set to a temperature of not less than 140°C above ambient and the oven shall be switched on after closing all adjustable vents. The time taken by the oven to reach the steady temperature of 100°C above the ambient shall be the heating-up time.

9.2.4 From lot of thermostats for use in the sterilizers, three samples shall be subjected to the performance test as described in **49** of IS : 302-1973*.

9.2.5 *Temperature Variation Test* — With temperature sensing elements located as described in **9.1.4.2**, the temperature differences shall be read with reference to the sensing element at the centre of the working space. The temperature variation at each point shall be determined by taking the mean of at least three readings of temperature difference at that point. The maximum temperature variation between any two points tested shall not exceed 3°C.

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*General and safety requirements for household and similar electrical appliances (*fourth revision*).

9.2.6 *Temperature Differential Test* — With a temperature sensing element located successively at all the different points described in **9.1.4.2**, or a number of sensing elements located simultaneously at all the points described, the temperature at each point shall be recorded continuously or at intervals not exceeding 5 minutes during a three hour test period. The temperature differential measured at any point shall not exceed 2°C.

9.2.7 *Temperature Drift Test* — With the oven adjusted as required by **9.1.3**, the oven temperature shall be recorded once every hour with the thermometer described in **9.1.4.1**, for a continuous period of 8 hours. The temperature drift so measured shall not exceed 2°C.

9.2.8 *Test for Time of Temperature Recovery* — An oven temperature of 99°C shall be regained in not more than 20 minutes after the temperature has been reduced from an initial steady value of 100°C by opening the oven door fully for one minute.

9.2.9 *Test for Reproducibility of Temperature Setting* — At the end of the test as described in **9.2.7**, when the last temperature reading has been taken, the oven shall be switched off, but left otherwise undisturbed for 24 hours. At the end of this period the oven shall be switched on again for at least three hours without altering its temperature setting. At the end of this period the original temperature before switching off shall be regained to within 1°C.

9.2.10 *Temperature Overshoot Test* — In the above test during the initial heating up, the temperature shall be recorded at least every 5 minutes when the temperature approaches the original temperature in the test according to **9.2.8** within 5°C, until a steady temperature is attained again. The maximum temperature recorded shall not exceed the steady sterilizer temperature finally obtained by more than 2°C.

INTERNATIONAL SYSTEM OF UNITS (SI UNITS)

Base Units

Quantity	Unit	Symbol
Length	metre	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Luminous intensity	candela	cd
Amount of substance	mole	mol

Supplementary Units

Quantity	Unit	Symbol
Plane angle	radian	rad
Solid angle	steradian	sr

Derived Units

Quantity	Unit	Symbol	Conversion
Force	newton	N	1 N = 0·101 972 kgf
Energy	joule	J	1 J = 1 N.m
Power	watt	W	1 W = 1 J/s
Flux	weber	Wb	1 Wb = 1 V.s
Flux density	tesla	T	1 T = 1 Wb/m^2
Frequency	hertz	Hz	1 Hz = 1 c/s (s^{-1})
Electric conductance	siemens	S	1 S = 1 A/V
Pressure, stress	pascal	Pa	1 Pa = 1 N/m^2

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